TESTIMONY OF JAMES M. WOOTTON

Before the

Health Subcommittee

of the

House Energy and Commerce Committee

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Summary

The current tort-based medical liability system – even after the usual reforms – does not well serve the interests of patients or healthcare professionals nor will it facilitate desirable healthcare transformation. There are better alternatives.

Advocates of medical liability reform should put more emphasis on patient safety and put liability reform in the context of a broader healthcare transformation agenda. The healthcare industry and policymakers could offer a new contract with the public — "We will do all we can to reduce the avoidable risks of medical treatment but also will provide a fair, fast and accessible system to compensate patients when avoidable injuries do occur." Patients are concerned about access to healthcare, but they also want to improve patient safety, find new cures for diseases, expedite drug approval, improve doctor-patient relationships and increase patient literacy.

Today, the tort system is seen as an impediment to the free exchange of information related to medical errors and adverse events. The Institute of Medicine (IOM) has repeatedly declared that patient safety is hindered by our current system of legal liability which discourages the disclosure of the very information that could reduce avoidable medical errors. As the IOM found, it is not mistakes by doctors that cause most medical injuries – it is system errors or an absence of a system. Therefore, I am suggesting the creation of a National Medical Data Center at the federal level and Patient Safety and Compensation Systems at the state level where the medical liability system is seen as a component of a much larger patient safety system. These new systems would facilitate – not inhibit – positive healthcare transformation and serve the interest of all the stakeholders in our healthcare system.

The country is at a crossroads in dealing with healthcare – either moving toward more government involvement and control or focusing on better defining and executing the government's necessary role in a market-based healthcare system that maximizes individual freedom and provides the necessary incentives for hard work and innovation. The goal of this legislation would be to provide the leadership and expertise needed to overcome inertia and move the country toward a shared vision of a transformed healthcare system. It also recognizes that legal reform is a critical step on that path. To pass this legislation and, indeed, to achieve the broader goals of healthcare transformation will require bipartisan cooperation and a coordinated effort by employers, health insurers, medical professionals and medical manufacturers with patient and consumer groups.

It is reasonable to conclude that widespread adoption of some version of this systematic approach to medical liability and the electronic medical systems that promote patient safety could save the country as much as $114 billion out of the $1.6 trillion currently spent on healthcare annually and, more importantly, thousands of lives.

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Thank you, Mr. Chairman, for the opportunity to share my perspective on the shape the next generation of national medical liability reform might take and its potential contribution to the goal of transforming our healthcare system to better serve the needs of patients. I want to make clear that while I have discussed these ideas with many stakeholders in the healthcare system, the views I share today are my own. In my opinion the current tort-based medical liability system – even after the usual reforms are implemented – does not well serve the interests of patients or healthcare professionals nor will it facilitate desirable healthcare transformation. There are better alternatives.

At a time when the viability of the current reform approach as embodied in HR 5 is being questioned, versions of which have passed the House eight times but have never passed the Senate, proponents of reform have the opportunity to reframe the debate.

Access to Medical Care

If the rationale given for medical liability reform is limited to the argument that high malpractice premiums reduce access to medical care because in one way or another medical professionals will withhold their services – by moving out of state, retiring, even choosing not to become a doctor – then the focus tends to be on the needs of the doctor. While these arguments are valid – even compelling – they have not been sufficient to create broad, bi-partisan support for reform at the national level.

Advocates for reform should put more emphasis on patient safety and put liability reform in the context of a broader agenda of healthcare transformation. What do patients and their advocates care about? What would a transformed healthcare system look like? And in what ways is the current medical liability system impeding progress toward that vision?

Successful legal reform efforts in the past have had three common elements: 1) a benefit to consumers and potential plaintiffs; 2) balance and fairness; and 3) sufficient stakeholder unity. The surprise passage of a very comprehensive Y2K Liability Act in 1999 had all of these elements – including the passionate support of the high tech industry, which is a very attractive constituency for both political parties. Successful federal medical liability reform will need those elements as well.

A New Contract with Patients

Putting more emphasis on patient safety would allow the healthcare industry and policymakers to offer a new contract with the public — "We will do all we can to reduce the avoidable risks of medical treatment and will provide a fair, fast and accessible system to compensate patients when avoidable injuries do occur."

Without question, access is chief among patient concerns. As you know, enormous intellectual and political effort is going into making healthcare more accessible – the Medicare Drug Benefit, Healthcare Savings Accounts, CMS reimbursement policies and coverage for the uninsured, etc. The cost issues top many stakeholders' agendas.

But patients and their advocates also care about the quality of the healthcare system to which they have access. They care about improving patient safety, finding new cures for diseases, expediting drug approval, improving doctor-patient relationships and improving patient literacy.

There are many passionate advocates for adopting policies that will facilitate healthcare transformation made possible because of advances in information technology and understanding of the human genome. In a 2004 speech at the National Press Club, Senator Frist painted a

compelling picture of the future healthcare system he would like to see by introducing the audience to a fictional patient from the year 2015:

> The patient, Rodney Rogers, is a 44-year-old man from the small town of Woodbury, Tennessee. He has several chronic illnesses, including diabetes, hypercholesterolemia, and hypertension. He is overweight. He quit smoking about eight years ago. His father died in his early 50s from a massive myocardial infarction. In 2005, Rodney chose a health savings account in combination with a high-deductible insurance policy for health coverage.
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> Rodney selected his primary medical team from a variety of providers by comparing on-line their credentials, performance rankings, and pricing. Because of the widespread availability and use of reliable information, which has generated increased provider-level competition, the cost of healthcare has stabilized and in some cases has actually fallen, whereas quality and efficiency have risen. Rodney periodically accesses his multidisciplinary primary medical team using e-mail, video conferencing, and home blood monitoring. He owns his privacy-protected, electronic medical record. He also chose to have a tiny, radio-frequency computer chip implanted in his abdomen that monitors his blood chemistries and blood pressure.
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> Rodney does an excellent job with his self-care. He takes a single pill each day that is a combination of a low dose of aspirin, an angiotensin-converting–enzyme (ACE) inhibitor, a cholesterol-lowering medication, and a medication to manage his blood sugar. That's one pill daily, not eight. He gets his routine care at his local clinic. He can usually make a same-day appointment by e-mail.
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> Unfortunately, chest pain develops one day while Rodney is on a weekend trip several hundred miles from home. The emergency room physician quickly accesses all of Rodney's up-to-date medical information. Thanks to interoperability standards adopted by the federal government in 2008, nearly every emergency room in the United States can access Rodney's health history, with his permission. The physician diagnoses an evolving myocardial infarction by commanding Rodney's implanted computer to perform a series of rapid diagnostic tests. The cardiologist in the "nanocath" lab injects nanorobots intravenously, and remotely delivers the robots to Rodney's coronary arteries. The tiny machines locate a 90 percent lesion in the left anterior descending coronary artery and repair it.
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> The hospital transmits the computerized information about Rodney's treatment, seamlessly and paperlessly, to Rodney's insurer for billing and payment. The insurer pays the hospital and physicians before Rodney returns home. Payments are slightly higher to this hospital than to its competitors because of its recognized high quality and performance. Rodney's hospital deductible and co-insurance are automatically withdrawn from his health savings account. Because Rodney has met

all his self-management goals this year, he gets a 10 percent discount on the hospital deductible.

Senator Frist concluded that: "Rodney's world is the future. The high-quality, rich information and common-sense efficiency inherent in Rodney's care are all within our grasp. In fact, we have seen similar and even greater transformations in equally complex sectors of our economy. It is time that healthcare follows the rest of our competitive economy and information society into the 21st century."

All those who would like to see such a system in the future should be asking whether our current tort-based medical liability system will help or hinder our efforts to achieve that vision. Or, whether politically achievable patient safety and compensation systems would better serve that vision and the interests of patients.

Problem with Current Medical Liability System

There are many problems with the current tort-based liability system which have been well-documented elsewhere.

Access/Cost:

- The current system is creating a shortage of providers.
- Fear of litigation causes physicians to practice defensive medicine.
- The current system raises healthcare costs generally, often beyond the reach of the most vulnerable.

Inefficiency:

- The current system provides inadequate compensation to injured patients.
- Injured persons face a lengthy wait before receiving compensation.
- Litigation includes high transaction costs which substantially reduce actual payments to plaintiffs.

Innovation:

- Litigation slows down the cycle of innovation and impedes the FDA approval process.
- Litigation increasingly involves layperson juries often second-guessing FDA science-based determinations.
- The current liability system has adversely impacted women's health.
- Litigation concerns cause safe and effective drugs to be withdrawn or completely withheld from the market.

Doctor-Patient Relationships:

- Inhibits communication between doctors, their patients and their colleagues.
- Litigation-related advertising causes patients to stop taking properly prescribed medicines.
- Fear of litigation causes some doctors not to prescribe medicines they believe are appropriate.

Patient Literacy:

- Litigation concerns contribute to confusing communications on drug labels, patient packet inserts and other patient information.

Use of Electronic Medical Records and Systems:

- Many doctors and hospitals fear that electronic medical records will be used as a resource for litigation by lawyers.

Misplaced Trust

My perception is that the only reason the public endures a medical liability system that contributes to so many problems is that it believes aggressive personal injury lawyers are essential to keep doctors and medical manufacturers honest. They may also believe that the medical industry has too much influence over the government bodies designed to protect the public, such as state medical boards and the FDA. The plaintiffs bar often uses those fears to justify asking their political allies to block reforms of the current tort-based medical liability system.

However, in looking at this question eSapience, a think-tank in Cambridge, Massachusetts, found there are many who question whether the current medical liability system helps or hinders patient safety. In a 1999 study the Institute of Medicine (IOM) estimated that as many as 98,000 Americans die each year as a result of preventable medical errors. Many of these deaths result from errors caused by the misuse of drugs and medical devices regulated by the FDA. The IOM and others also suggest that more than half the errors that underlie those deaths can be linked to failed systems and procedures that are poorly designed to accommodate the complexity of healthcare delivery.

Seven years later, improvements in patient safety can be seen at the margin, but much work is left to be done. Technology can pave the way toward improved patient outcomes across the healthcare delivery system. It can help healthcare providers, the FDA, and drug manufacturers navigate the complexity of the healthcare system by systematically capturing, distributing, analyzing and safeguarding the essential information needed to support decision-making. Better information can also benefit patients and their doctors by reducing avoidable medical errors and adverse events related to the administration of prescription drugs and biologics, and in some cases, accelerating the drug approval process.

Technology is an essential component of a healthcare system that has safety and patient well being as its overarching priority. Such a system must also be designed around a set of incentives for all healthcare stakeholders to contribute willingly and act upon that information. Today, the tort system is seen as an impediment to the free exchange of information related to medical errors and adverse events. The IOM has repeatedly declared that patient safety is hindered by our current system of legal liability and the overhanging threat of litigation, which discourage the disclosure of the very information that could reduce avoidable medical errors.

The current approach focuses too little on changing systems to improve patient safety and too much on punishing individuals or companies who are alleged to be at fault. The punitive nature of the tort system creates an incentive to conceal information for as long as possible if there is an allegation of injury. It also forces densely worded prescription drug labeling in an effort to cover all possible adverse outcomes, which is confusing to doctors and their patients. The tort system thwarts the important principle of shared knowledge, which makes it difficult to learn in real time from others. It was shared knowledge that dramatically cut the response time to the SARS epidemic. This principle is considered critical to the successful results of other industries where consumer safety is tantamount. The airline, nuclear energy and chemical industries, for example, all have non-punitive surveillance systems that foster the exchange of information and which is said to help these industries avert the great majority of all accidents or injuries.

As the IOM report has suggested, patient safety is also made more difficult given the sheer complexity of the healthcare system itself. The delivery of healthcare involves the careful orchestration of a dynamic network of people and processes that must work together to deliver care to patients. According to Professor James Reason, the healthcare system has more than 50 different types of medical specialties and subspecialties interacting with each other and with an equally large array of allied health professions. Efforts to improve patient safety must, therefore, focus on what is needed to improve the inter- and intra-workings of this overall system. Prior efforts to reform patient safety and medical malpractice have focused on worthy, but narrow silos. They have not always been effective because they did not adequately address the interaction of a specific reform on the overall system.

If the IOM report is correct – that it is bad systems and not bad people or companies that led to the majority of medical errors and injury – then a piecemeal approach to reform will not create the sea-change needed to advance a national patient safety agenda. Reducing medical errors and minimizing adverse events related to the manufacture and use of prescription drugs will hinge on the design of a system that makes wrong actions by those with a stake in healthcare delivery more difficult; makes it easier for those entrusted with ensuring patient safety to discover the errors that could occur before they do; and provides patients with just compensation in the event they are injured.

It Takes a System

As the IOM found, the problem is not mistakes by doctors that cause most medical injuries, it is system errors or an absence of a system. Therefore, Congress should encourage the creation of Patient Safety and Compensation Systems at the state level where the medical liability system is seen as a component of a much larger patient safety system. These new systems would facilitate – not inhibit – positive healthcare transformation and serve the interest of all of the stakeholders in our healthcare system. The four pillars of improving the capacity and quality of our healthcare systems are Information, Infrastructure, Incentives and Innovation:

- Information is essential to improving doctor/patient decision making, reducing medical errors, minimizing redundancy, enabling research and reducing illness and disease;
- Infrastructure is essential so that information can be accurately, efficiently and confidentially captured, exchanged and efficiently analyzed;
- Incentives drive the behavior of doctors, patients, employees, insurers and manufacturers of health-related products; and
- Innovation produces new preventatives, new tools for diagnoses and new treatments for illness and disease.

National Medical Data Center

It now appears both technically and politically possible to create the capability at the national level of accessing on a real-time basis medical data (data that cannot be used to identify the patient or the healthcare professional) from an ever-increasing pool of electronic medical records. Realistically, this goal could not be achieved overnight. At the present time, only a small percentage of patients have Electronic Medical Records (EMRs). The data in those records are uneven, non-standardized and as one expert said "getting doctors to include data that is not clinically useful will be a challenge." However, there are an increasing number of efforts to mine the electronic claims data of medical insurance companies which are producing immediately useful information as well as providing signals suggesting closer scrutiny of the paper files.

Eventually these EMRs would contain sufficient standardized data (or data that could be translated to standard terms) to allow studies by government, academic and industry researchers to reach valid scientific conclusions regarding effective treatment protocols, strategies for avoiding medical errors and adverse event and promising paths in the search for cures for disease. The availability of such a database could greatly reduce the marginal cost and time needed to do valid scientific studies and could fuel a dramatic increase in effective medical research. Such a database, even as it matures, also would aid HHS, CMS, FDA, DHS and CDC in fulfilling their missions.

Experience-rated Compensation Systems

At the heart of this vision is an experience-rated administrative compensation system and trusted regulators focused on patient safety. The premise of this approach is that a compensation system with a relatively low cost of claiming for the patient will drive up the standard of care and

reduce medical errors more effectively than the more random tort system. It is fairly well accepted that raising the likelihood of detection deters unwanted conduct more effectively than extreme, random and unpredictable penalties. If, as expected, the use of electronic medical records and practice aids which reduce medical errors becomes the standard of care for certain treatments, this liability system will produce powerful incentives for their adoption and help drive positive healthcare transformation.

The idea of administrative courts is not unique. Social Security, Workers Comp, the Childhood Vaccine Fund – even Bankruptcy Courts – all operate without juries and because of various features of due process have been held to be constitutional. The feature of a Patient Safety and Compensation System that makes it somewhat unique is the way in which the components would interact.

Medical Claims Facility:

If a patient – who was a resident of that state – thought that he or she had been injured as a result of medical treatment by a medical provider in that state, then the patient could contact that state's Medical Claims Facility – operated by the Medical Providers Insurance Facility comprised of insurers who write insurance for doctors, hospitals and nursing homes in that state.

Claims Assistant:

The patient would be assigned a Claims Assistant (think paralegal) who, though not an advocate for the patient, would help the claimant pull together his or her medical file, make sure the claims forms were complete and submit them to the Claims Facility Medical Staff. The same Claims Assistant would be assigned to the patient for the duration of the claims process.

Medical Staff:

The Medical Staff would notify the professional(s) involved and his or her malpractice carrier and would compare the claims forms and medical file against the practice guidelines issued by the Medical Practice Commission. The Medical Staff would make a determination whether the evidence indicated that the medical provider had met the applicable standard of care. If there were no applicable guidelines, then the Medical Staff would ask the Medical Practice Commission to analyze the facts of that particular case and issue an opinion as to whether the professional had met the applicable standard of care. The Medical Staff would also be authorized to require an independent medical exam at no expense to the patient.

Medical Providers Insurance Facility:

Once the Medical Staff concluded that the claimant should be paid, a claims processor would contact the patient and offer to settle his or her claim. If the patient agreed to settle, then the Medical Providers Insurance Facility, which would operate like a Joint Underwriting Association, would pay the claim with funds provided by the provider's malpractice insurer. Ideally, the state would not subsidize these awards.

The Medical Providers Insurance Facility, which would have an incentive to reduce medical errors and a mechanism for insurers to act collectively, would also direct loss reduction programs to reduce the number of medical errors in the state. In egregious cases, the Facility would also make referrals, along with the Administrative Medical Court to the Patient Safety Board, for possible action against the professional.

All medical providers, including nursing homes, would be required to have medical malpractice or other insurance which was experience-rated based on the providers safety record.

If a provider, based on a history of malpractice claims, could no longer prove financial responsibility, it could not operate in the state.

Administrative Medical Court:

If the patient did not accept the offer, which could be governed by some form of "early offer" incentives, then he or she could ask for a hearing in front of an Administrative Medical Court Judge. The Judge could take testimony, allow discovery and otherwise conduct a civil trial. While parties could have lawyers and retain their own experts, the Judge would rely heavily on the opinion of *Daubert* qualified experts working on behalf of the State Medical Commission which would be expected to apply nationally accepted standards of care to the particular circumstances of cases that come before the Medical Practice Commission and Administrative Medical Court.

Medical Practice Commission:

The Medical Practice Commission would be appointed by the Governor and made up exclusively of *Daubert* qualified experts in medical practice. It would be essential that Commission members have the support of the medical specialty groups in the state. If a state's system handles claims against medical manufacturers, then the Commission should include *Daubert* qualified experts to make determinations whether a particular medical product or device is the likely cause of a medical injury.

Courts of Appeals:

If either party is not happy with the Medical Court's decision, then the party may appeal the decision "on the record" to whatever state courts of appeal have jurisdiction.

Patient Safety Board:

A Patient Safety Board appointed by the governor and confirmed by the legislature would have authority to order further training, suspend or revoke a medical providers license and/or impose appropriate fines. The Board would have representatives of both the professional and patient communities.

Patient Safety Data:

The whole system would rely on evidence-based medical data accumulated by government agencies, safety organizations or other credible sources including the National Medical Data Center.

State Electronic Healthcare Initiative:

A state electronic healthcare initiative involving all stakeholders would provide the leadership to set the standards, overcome silos and seek funding mechanisms to achieve adoption, interoperability and functionality for electronic medical records and electronic medical systems.

"Keep America Healthy Campaign"

The Congress and Administration, with or without legislation, could encourage public/private partnerships to encourage healthy behaviors and the creation of a culture of health. Most policymakers in and out of government focus on the cost of treatment side of the healthcare cost equation where "cost equals incidences of disease times cost of treatment." It is time for America to focus more attention on lowering the incidences of disease. While there are many community and corporate disease prevention programs being undertaken already, a concerted effort that more effectively organizes and mobilizes our national resources would have a better chance of changing behavior and positively affecting culture. Lady Byrd Johnson's "Keep

America Beautiful Campaign" dramatically reduced the incidence of roadside litter. A "Keep America Healthy Campaign" would do the same for the incidence of debilitating and costly diseases.

Federal Legislation

To encourage the creation of Patient Safety and Compensation Systems along the lines outlined, Congress has many choices about how best to provide leadership and incentives. There are substantial Federal interests to justify taking action including the Medicare and Medicaid programs, the Medicare Drug Benefit, the interstate nature of the healthcare and health insurance industry and the interstate nature of large employers for whom these reforms could be critical in saving American jobs. Therefore, I urge Congress to consider legislation that deals with the issues discussed.

Patient and Safety and Compensation Act
(A Legislative Concept)

Title I – National Medical Data Center

The National Medical Data Center would make available to authorized users the real-time, privacy-protected data from as many as 12 million electronic medical records nationwide.

Title II – Electronic Health Initiative

The Act could create national uniform standards as needed to facilitate and provide formula grant funding and technical assistance to the States for electronic health systems to improve patient safety, lower costs and improve medical care. Formula grants would be subject to certain conditions and criteria to ensure the funds are put to their intended use.

Title III – Uniform State Medical Liability Standards

This title would contain politically achievable Federal preemptive standards in recognition of the fact that state healthcare liability systems do have a substantial impact on

interstate commerce and that national healthcare transformation can be impeded by a single state legal system that imposes unreasonable and damaging liability standards on a national market for medical services and products.

The items that follow have been suggested as belonging in any new Medical Liability Reform (MLR) legislation. They are listed here as placeholders only, and there may be some items on the list that should be deleted/modified; there may be some "missing" items that need to be added.

- Federal standards for medical liability litigation in federal or state court
- Scope of bill's application (persons/entities; definitions)
- Scope of legislation – ERISA and related issues
- Speedy resolution of claims through statute of limitations changes
- Limits on non-economic damages or keep existing state limits
- Damages apportioned by "fair share" rule, i.e., no joint and several liability
- Limits on attorney contingency fees
- Standards for "expert witnesses"
- Use of Medical Screening Boards/Panels
- Adoption of "I'm Sorry" programs
- Independent External Medical Review
- Reduction in awards for collateral sources
- Limits on and/or standards for punitive damages
- Periodic (not lump sum) payments (use federal standards to comply)

Title IV – Alternative State Medical Liability Systems

Title IV would encourage and facilitate the creation of new healthcare liability systems that are patient safety focused along the lines of the Patient Safety and Compensation System. It would provide incentives and guidelines for states to create demonstration programs to test alternatives to current medical tort litigation. Funding to states under this title would cover planning grants for the development of proposals for alternatives, and would also include the initial costs of getting those alternatives up and running. The legislation also would require participating states and the federal government to collaborate in continuous evaluations of the results of the alternatives as compared to traditional tort litigation.

Conclusion

This holistic approach to healthcare allows focus on three key goals:

- More effective prevention of illness and disease;
- Early diagnosis; and
- More efficient and effective treatment.

The goal of the Patient Safety and Compensation Act would be to provide the leadership and expertise needed to overcome inertia and move the country toward a shared vision of a transformed healthcare system. It also recognizes that legal reform is a critical step on that path. To pass this legislation and indeed to achieve the broader goals of healthcare transformation will require bipartisan cooperation and a coordinated effort with employers, health insurers, medical professionals, and medical manufacturers working collaboratively with patient and consumer groups.

It is reasonable to conclude that widespread adoption of some version of this systematic approach to medical liability and the electronic medical systems that facilitate patient safety could save the country $114 billion or more out of the $1.6 trillion currently spent annually on healthcare. According to a January 2005 article in the Journal of Health Affairs, savings could be as much as:

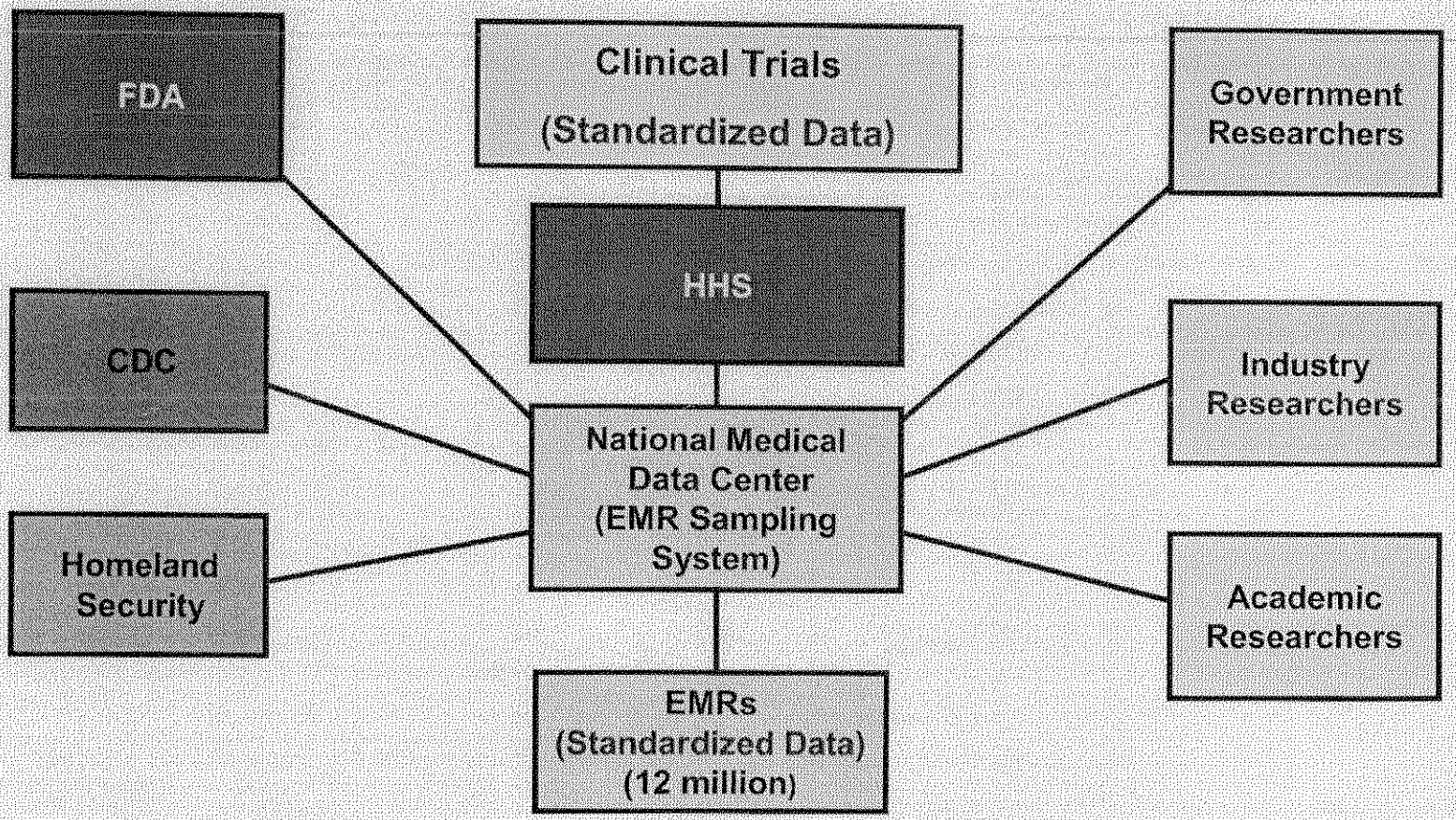
$ 78 Billion for delivery and administration
$ 29 Billion for avoidable medical errors
$ 7 Billion for non-meritorious legal actions
$114 Billion

Most importantly, the article also predicted a reduction in medical errors which could save over 7,000 lives a year.

An initiative of this scope will require Congressional leadership. Only Congress can insist on stakeholders working together to work out their differences, encourage the

compromises that allow progress toward a common goal and enforce the discipline that prevents " freelance" lobbying from killing such an important legislative initiative. Again, Mr. Chairman, thank you for the opportunity to share my perception on these issues, and I look forward to any questions you or your colleagues may have.

National Medical Data Center
(With Privacy and Liability Protections)



State Patient Safety & Compensation System